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10/533,846	11/11/2005	Jacques Beaurain	LDR/10/US - 21249.014US1	7881
26201	7590	10/15/2008	EXAMINER	
FISH & RICHARDSON P.C. P.O BOX 1022 Minneapolis, MN 55440-1022			YANG, ANDREW	
			ART UNIT	PAPER NUMBER
			3775	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/533,846	Applicant(s) BEAURAIN ET AL.	
	Examiner ANDREW YANG	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-30, 33-50, 52 and 54-64 is/are rejected.
- 7) ☒ Claim(s) 31, 32, 51 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicants' amendment filed on 6/25/2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 27, 28, 36, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (U.S. Patent No. 6368350).

Erickson et al. discloses an intervertebral disc prosthesis 10 with upper plate 20, a lower plate 21, and a core 22. The core 22 has an upper surface 46 that is in contact with a lower surface 25 of the upper plate 20 and a lower surface 47 of the core 22 is in contact with an upper surface 28 of the lower plate 21. The upper plate 20 is moveable with respect to the core 22 and the core 22 is moveable in translation and rotation with respect to the lower plate 21 (Column 7, Lines 30-35). There are cooperation means not located in the middle of the core between the lower plate and the core to limit translation movements of the core with respect to the lower plate around an axis parallel to the lower plate 21 and means to limit rotational movements of the core with respect to

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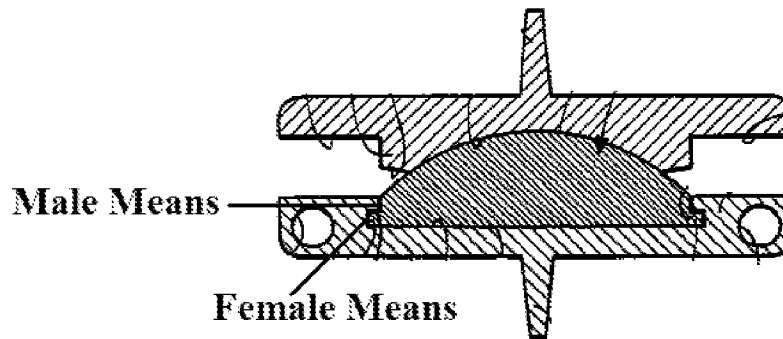
the lower plate around an axis perpendicular to the lower plate 21 (Column 7, Lines 65-67). The core can be made of polyethylene (Column 5, Lines 58-60). Furthermore, the lower surface 25 of the upper plate 20 is concave and complimentary to the upper surface 46 of the core 22 (Column 7, Lines 14-21). Furthermore, the intervertebral disc prosthesis can have one circular opening 410 along its front side (Figure 33) to receive an anchoring means in the form of screws (Column 9, Lines 60-64) and are considered nail shaped.

Claims 21-23, 30, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Marnay et al. (U.S. Patent No. 6936071).

Marnay et al. discloses an intervertebral implant with an upper plate 2, a lower plate 3, and a core 4. Core is made of polyethylene (Column 5, Line 37), has an upper convex surface 25 in contact with the lower concave surface 12 of the upper plate 2 and a lower surface in contact with the upper surface of the lower plate 3, with the upper plate 2 being moveable with respect to the core 4 (Column 5, Lines 43-53). The lower plate has cooperation means 27 not located in the middle of the core between the lower plate and the core. The cooperation means serves to fix the core 4 to the lower plate 3 (Column 5, Lines 16-19), thus limiting translation movements with respect to the lower plate around an axis parallel to the lower plate, and rotation movements with respect to the lower plate around an axis perpendicular to the lower plate. With reference to the figure on the next page, the cooperation means has a male means and a female means. The male means cooperates with a female means of the core 4, and the female means of the lower plate cooperates with a male means of core 4. In both cases the

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cooperating means of the lower plate 3 have substantially the same dimensions of the cooperating means of the core 4.



The cooperation means, is also comprised of a stop, with a male portion and a female portion located along an edge of the prosthesis as seen in the figure above. Furthermore, the core 4 is considered translatable with the lower plate since it is slide into place along an axis parallel to the lower plate, and can be rotated about an axis perpendicular to the lower plate prior to full insertion of the core. The female portion is disposed on the lower plate and the male portion 26 is disposed on the core. But it can also be seen that the core has a female portion that cooperates with the male means on the lower plate. The female portion can be considered a recess and groove above element 26 and the male portion is part of a wall.

Claims 21, 22, 29, 33, 35, 41, 47-50, 56, and 62-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Pisharodi (U.S. Patent No. 6610093).

Pisharodi discloses an intervertebral disc prosthesis 10G having an upper plate, a lower plate, and a core 26G. An upper surface of the core is in contact with a lower surface of the upper plate and a lower surface of the core is in contact with an upper surface of the lower plate (Figure 6). The core 26G can be considered to have a curved

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upper surface since ball socket 38G is part of the upper surface and is curved to be in contact with a curved surface 41G. Ball 41G is considered to be a part of the lower surface of the upper plate. The upper plate is moveable with respect to the core and the core is moveable in translation and rotation with respect to the lower plate (Column 5, Lines 14-24). There are cooperation means 94G not located in the middle of the core so as to limit translation movements around an axis parallel to the lower plate and to limit rotation movements of the core with respect of an axis perpendicular to the plate (Column 5, Lines 20-24). The lower plate has the male means 94G cooperating with the female means 90G of the core (Figure 6). The dimensions of the male means are less than those of the female means (Column 5, Lines 20-24).

With regard to claim 33, elements 94G can also be considered male means that are located near the center of the lower plate since they are near the center line of the lower plate (Figure 6) and the female means 90G can be considered wells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Patent No. 6368350) in view of Graf (U.S. Patent No. 6419706).

Erickson et al. discloses the claimed invention and also further discloses the used of a second core that has a thickness that differs from the thickness of the first core (Column 9, Lines 39-40). Erickson et al. fails to disclose the core forming an acute angle in a front-rear direction. Graf teaches an intervertebral disc with a core 4 and upper and lower plates 6. The core 4 has a greater transverse dimension at its front part than at its rear, forming an acute angle from front-rear direction, which gives the device a lordosis appearance, which is found to be advantageous from a physiological point of view (Column 9, Lines 57-59). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Erickson et al. with a core that forms an acute angle in the front-rear direction in view of Graf so that the device would have a lordosis appearance that is physiologically advantageous.

With regard to claim 26, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Erickson et al. as modified by Graf with the angle between the upper and lower plates to be between 0 and 15 degrees, since it has been held that where the general conditions of a claim are

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disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Patent No. 6368350).

Erickson et al. discloses the claimed invention except for the openings being rectangular. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the holes of Erickson et al. with a rectangular shape, since applicant has not disclosed that such solves any stated problem or is anything more than one of numerous shapes or configurations a person with ordinary skill in the art would find obvious for the purpose of providing an anchoring means into adjacent vertebrae. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 40-47, 52, 55, 56, 57, 58, 59, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (U.S. Patent No. 6368350) in view of Pisharodi (U.S. Patent No. 6610093).

Erickson et al. discloses an intervertebral disc 10 with an upper plate 20, a lower plate 21, and a core 22. As seen in Figures 6 and 7, the upper plate 20 has a curved convex surface that contacts a curved concave surface of the core 22. This arrangement can be reversed with the core having a convex surface and the upper plate having a concave surface (Column 7, Lines 15-20). The lower surface of the core is planar (Figure 6). The upper plate 20 is moveable with respect to the core 22 and the core 22 is moveable in translation and rotation with respect to the lower plate 21 (Column 7, Lines 30-35). Furthermore, the intervertebral disc prosthesis can have one

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circular opening 410 along its front side and back side (Figure 33) to receive an anchoring means in the form of screws (Column 9, Lines 60-64) and are considered nail shaped. There are cooperation means not located on the edge of the implant between the lower plate and the core to limit translation movements of the core with respect to the lower plate around an axis parallel to the lower plate 21 and means to limit rotational movements of the core with respect to the lower plate around an axis perpendicular to the lower plate 21 (Column 7, Lines 65-67).

Erickson fails to disclose the means to limit rotation to comprise a male portion and a female portion located along an edge. Pisharodi teaches an intervertebral disc prosthesis 10G having an upper plate, a lower plate, and a core 26G. The upper plate is moveable with respect to the core and the core is moveable in translation and rotation with respect to the lower plate (Column 5, Lines 14-24). There are cooperation means 94G (male means/stop) and 90G (female means/recess) not located in the middle of the core so as to limit translation movements around an axis parallel to the lower plate and to limit rotation movements of the core with respect of an axis perpendicular to the plate (Column 5, Lines 20-24) and allow for the normal range of motion (Column 5, Lines 31-36). Both Erickson and Pisharodi disclose an intervertebral implant having upper and lower members with a core moveable with respect to the lower member in translation and rotation and means to limit the translation and rotation of the core. Thus it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Erickson with means to limit rotation to comprise a male portion and a female portion located along an edge of the implant in view Pisharodi. Providing

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the limit means of Pisharodi on the device of Erickson would have been obvious to try since such a design has been shown by Pisharodi to allow for a normal range of motion.

With regard to claim 40, 43 and 58, it would have been obvious to one skilled in the art at the time the invention was made to construct the device of Erickson with the upper plate having a convex upper surface in view of Pisharodi in order to account for the anatomy of the vertebral end plates (Column 2, Lines 4-6).

With regards to claims 52, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the male means of the lower plate with curved pins towards the inside of the prosthesis to engage a recess or a tagged fixed by a dowel, or a wall, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a means for limiting motion. In re Dailey and Eilers, 149 USPQ 47 (1966).

With regard to claim 46, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with the female means on the lower plate and the male means on the core, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (U.S. Patent No. 6610093) in view of Graf (U.S. Patent No. 6419706).

Pisharodi discloses the claimed invention except for the core forming an acute angle in a front-rear direction. Graf teaches an intervertebral disc with a core 4 and

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upper and lower plates 6. The core 4 has a greater transverse dimension at its front part than at its rear, forming an acute angle from front-rear direction, which gives the device a lordosis appearance, which is found to be advantageous from a physiological point of view (Column 9, Lines 57-59). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Pisharodi with a core that forms an acute angle in the front-rear direction in view of Graf so that the device would have a lordosis appearance that is physiologically advantageous.

Allowable Subject Matter

Claim 31, 32, 51 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicants contend that Erickson fails to disclose a cooperation means not located in the center of the core to limit translational and rotational movements of the core. As cited by the Examiner, and also by the Applicants, Column 7, Lines 65-67 in brief discloses, means to limit rotational or translational freedom provided at the planar bearing surface 51. This can be construed to mean that the rotational and translational freedom of the core is limited since only the core rotates and translates with respect to the bearing surface 51. The bearing surface being apart of the lower member does not rotate or translate.

Applicant's arguments with respect to Marnay et al. have been considered but are moot in view of the new ground(s) of rejection.

Arguments with respect to Pisharodi have been addressed in the body of the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3775
10/8/2008

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733